MAR - 6 2001

K002689

SWABSITE SWABBABLE VALVE
510(K) PREMARKET NOTIFICATION SUMMARY

1. SUMBITTER'S NAME:

Quest Medical, Inc.
One Allentown Parkway
Allen, Texas 75002
(972) 390-9800
(972) 390-2881 FAX

CONTACT PERSON:

Doug Bryan
QA Manager

DATE PREPARED:

August 28, 2000

2. DEVICE NAME:

Proprietary Name: Swabsite Swabbable Valve

Common Names:

Intravascular Administration Set
Swabbable Valve

Classification Names:

Intravascular Administration Set
I.V. Fluid Transfer Set

3. PREDICATE DEVICE:

Smartsite Access Pin, K970485

4. DEVICE DESCRIPTION:

The Swabsite Swabbable Valve is a needle free valve that allows the user to add medication into IV sets without the use of a needle. When the valve is in the closed position it has a flat, smooth surface for cleaning. When the male connector of a syringe or secondary line is pushed into the valve, the silicone stem opens in the middle creating a fluid path. When the male connector is removed from the valve, the body of the valve forces the stem shut and maintains a sealed fluid path. A cap is not required to seal the valve or to maintain sterility.

5. INTENDED USE:

The intended use for the Swabsite Swabbable Valve is to allow access to IV administration sets, medication vials, blood types, and solution bags with one

convenient device without the use of needles or blunt cannulas.

6. TECHNOLOGICAL CHARACTERISTICS:

The Swabsite Swabbable Valve allows needleless access to IV administration sets, medication vials, blood tubes, and solution bags. The technological characteristics of the device are similar to the Smartsite Access Pin (K970485) and raises no new questions of safety and effectiveness. Quest concludes that the SwabSite Swabbable Valve is substantially equivalent to current marketed devices.

7. NON-CLINICAL DATA:

The Swabsite Swabbable Valve has been shown to be substantially equivalent to the predicate device by non-clinical performance testing data. The testing involved performance testing, biocompatibility testing, and a microbial barrier challenge of the valves.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2001

Mr. Doug Bryan
Plant Quality Assurance & Regulatory Affairs Manager
Quest Medical, Incorporated
One Allentown
Allen, Texas 75002

Re: K002689
Trade Name: Swabsite Swabbable Valve
Regulatory Class: II
Product Code: FPA
Dated: February 7, 20001
Received: February 8, 2001

Dear Mr. Bryan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) **K002689**

Device Name Quest Medical, Inc. Swabsite Swabbable Valve

Indications for Use The SWABSITE injection port is an IV administration set accessory that allows needleless luer connections to luer access devices (syringes, etc.)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Patricia Cuccinotta

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K002689